

REMARKS

In the Final Office Action mailed July 29, 2008, claims 1-14, 44-64, 67 and 69 were pending. Claims 1, 5-7, 11-14, 44-47, 51-57, 61-64, 67 and 69 stand finally rejected, and claims 2-4, 8-10, 48-50 and 58-60 were withdrawn. It is respectfully submitted that a prima facie case for obviousness of the rejected claims has not been established, and withdrawal of the final rejection is respectfully requested.

Claims 1, 5, 7, 11-14, 44, 45, 47, 51-56 and 60-69 were indicated to be rejected under 35 USC §103(a) as unpatentable over U.S. Patent No. 5,755,797 to Baumgartner in view of U.S. Patent No. 6,620,196 to Trieu. In the "Response to Arguments" on page 2 of the Final Office Action, the Examiner states "the Examiner does not understand why Applicant's representative is arguing on how the outer shell cannot rigidly fix the support members. For example, as previously discloses (sic) in the last office action, the outer shell that was injected into the intervertebral disc as a fluid (see col. 5, lines 20-67) is capable of covering the whole implant and all the implant voids to prevent expulsion. As shown in col. 5, lines 40-46, the outer shell provide (sic) flexibility to the implant."

It is respectfully submitted that it does not appear that Applicants' previous arguments were understood. Applicants' arguments were directed to the outer shell in Trieu not being able to rigidly fix the support members 7 of Baumgartner at the volume of the intervertebral space occupied by support members 7. The Examiner states that the outer shell in Trieu provides flexibility to the implant, and Baumgartner teaches support members 7 that are elastic and that elastically deform under stress from the loading of the spinal column. In contrast, Applicants' invention in claim 1 includes "means for rigidly fixing said plurality of reductions element at said volume in engagement with one another". Claim 1 also recites that the reductions elements are "selected in number to occupy a volume within the intravertebral space that reduces a vertebral fracture....." Since the reduction elements in claim 1 are rigidly fixed at the volume occupied by the reduction elements in the intravertebral space, post-operative maintenance of the reduction of the vertebral body is achieved since the volume is rigidly fixed. In contrast, the support members 7 of Baumgartner, which deform under stress from spinal column loading. and the flexible outer shell of Trieu, which permits deformation

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of support members 7 under stress, would not rigidly fix the support members 7 at the volume occupied by support members 7 in the disc space. Rather, the volume occupied by the support members 7 of Baumgartner is not rigidly fixed but varies in response to the stress from spinal column loading. Trieu does not remedy the deficiencies of Baumgartner since shell 10 is also elastic and flexible, and does not function to provide "means for rigidly fixing said plurality of reduction elements at said volume in engagement with one another in the intravertebral space for post-operative maintenance of the reduction of the vertebral body" as recited in claim 1. Therefore, the combination of Baumgartner and Trieu fail to teach or suggest all the features of claim 1 and a prima facie case for obviousness of claim 1 has not been established.

The examiner also states "[r]egarding the volume, the Examiner interpreted the volume as the whole resected patient's disc area. Therefore, the outer shell 30 would fix the volume of the elastic support member 7 of Baumgartner." The examiner further states "[r]egarding the elastic deformation, as mentioned above col. 5, lines 20-67 clearly disclose that the outer shell in (sic) capable of having flexibility. Additionally, col. 6, lines 62-56 clearly discloses elastic and flexible materials." As discussed above, claim 1 recites that the "said plurality of reduction elements are selected in number to occupy a volume...." While support members 7 in Baumgartner occupy a volume in the disc space, this volume occupied by support members 7 is not rigidly fixed by the elastic and flexible shell in Trieu since Baumgartner teaches support members 7 elastically deform under stress and Trieu teaches a flexible and elastic shell that also deforms. When deformed under stress, the support members 7 occupy a different volume than when not deformed, and the volume occupied by support members 7 thus is not rigidly fixed. Therefore, the references fail to teach or suggest claim 1 for this additional reason.

In the "Response to Arguments" the examiner also asserts that applicants made "arguments that the support members elastically deform under the stress" and then states "the Examiner wants to point out that those limitations are no where found in the claims." Applicant's representative has reviewed the prior response and cannot find any arguments where it was asserted the reduction elements in the claims elastically deform under stress. It was argued that support members 7 of Baumgartner are elastic and are taught to elastically

deform under stress from spinal column loading. It was further argued that this teaching of the elastically deforming support members 7 in Baumgartner teaches away from an arrangement where the support members 7 are rigidly fixed at a volume since support members 7 elastically deform when compressed to elastically support the spinal column and thus cannot include a rigidly fixed volume in the spinal disc space while elastically supporting the spinal column. As discussed above, Applicant's invention in claim 1 does not elastically deform under stress since it includes means for rigidly fixing the reduction elements at the volume occupied by the reduction elements for post-operative maintenance of the intravertebral reduction of a vertebral body.

Since claim 1 recites, among other features, "wherein said plurality of reduction elements are selected in number to occupy a volume within the intravertebral space that reduces a vertebral fracture and restores the vertebral body; voids between respective ones of said plurality of reduction elements; and means for rigidly fixing said plurality of reduction elements at said volume in engagement with one another in the intravertebral space for post-operative maintenance of the reduction of the vertebral body..." (emphasis added), the combination of Baumgartner and Trieu does not support a prima facie case for rejecting claim 1 and withdrawal of the rejection of claim 1 is respectfully requested.

The combination of Baumgartner and Trieu also fails to teach or suggest all the elements in claims 44 and 55. Claim 44 recites "a plurality of reduction elements positionable in an intravertebral space adjacent one another in contact with bony tissue, wherein said plurality of reduction elements act randomly and radially one upon the other upon sequential positioning thereof in the intravertebral space compressing cancellous bony tissue and applying an outwardly directed corrective force in the vertebral body, wherein said plurality of reduction elements are selected in number to occupy a volume within the intravertebral space that reduces a vertebral fracture and restores the vertebral body; voids between respective ones of said plurality of reduction elements; and material filling said voids and rigidly fixing said plurality of reduction elements at said volume in engagement with one another in the intravertebral space for post-operative maintenance of the reduction of the vertebral body, said material locking said plurality of reduction elements relative to one another."

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As discussed above, neither Baumgartner nor Trieu teach any material filling voids to rigidly fix support members 7 at a volume occupied by the support members 7 in the spinal disc space. Rather, support members 7 are selected in number to replace a core region of an intervertebral disk (3) and to elastically support the vertebrae. Furthermore, the volume occupied by support members 7 is not rigidly fixed since Baumgartner further teaches that "during loading, the support members are elastically deformed, and the compressive forces acting in the direction of the member axis are converted into edge stresses in the annulus fibrosus." See col. 1, line 62-65. The Office Action fails to identify any teaching or disclosure in Baumgartner that support members 7 have a rigidly fixed volume and these structural features in claim 1 cannot be read on Baumgartner since the compression of the elastic support members 7 prevents rigidly fixing the volume occupied by support members 7 of Baumgartner.

Furthermore, even if outer shell 30 in Trieu were placed around support members 7, outer shell 30 is not taught to rigidly fix support members 7 of Baumgartner at a volume occupied by the support members 7 in the spinal disc space. There is no teaching that outer shell 30 rigidly fixes the volume of elastic body 15, or that outer shell 30 would rigidly fix the volume of the elastic support member 7 of Baumgartner. Therefore, a prima facie case for rejecting claim 44 has not been established.

The combination of Baumgartner and Trieu also fails to teach or suggest all the elements in claim 55. Claim 55 recites "plurality of reduction elements positionable in an intravertebral space adjacent one another in contact with bony tissue, wherein said plurality of reduction elements include exterior surface means for facilitating engagement between adjacent reduction elements and for facilitating said reduction elements acting randomly and radially one upon the other upon sequential positioning thereof in the intravertebral space to compress cancellous bony tissue and apply an outwardly directed corrective force in the vertebral body, wherein said plurality of reduction elements are selected in number to occupy a volume within the intravertebral space that reduces a vertebral fracture and restores the vertebral body; voids between respective ones of said reduction elements; and material filling said voids and rigidly fixing said plurality of reduction elements at said volume in engagement with one another in the intravertebral space for post-operative maintenance of the

reduction of the vertebral body, said material locking said plurality of reduction elements relative to one another.”

As discussed above with respect to claims 1 and 44, neither Baumgartner nor Trieu teach any material filling voids to rigidly fix support members 7 at a volume occupied by the support members in the spinal disc space. Rather, support members 7 are selected in number to replace a core region of an intervertebral disk (3) and to elastically support the vertebrae. The volume occupied by support members 7 is not rigidly fixed since Baumgartner teaches that “during loading, the support members are elastically deformed, and the compressive forces acting in the direction of the member axis are converted into edge stresses in the annulus fibrosus.” See col. 1, line 62-65. The Office Action fails to identify any teaching or disclosure in Baumgartner that support members 7 have a rigidly fixed volume and these structural features in claim 1 cannot be read on Baumgartner since the compression of the elastic support members 7 prevents rigidly fixing the volume occupied by support members 7.

Even if outer shell 30 in Trieu were placed around support members 7, outer shell 30 is not taught to rigidly fix support members 7 at a volume occupied by the support members in the spinal disc space. There is no teaching that outer shell 30 rigidly fixes the volume of elastic body 15, or that outer shell 30 would rigidly fix the volume of the elastic support member 7 of Baumgartner. Therefore, a prima facie case for rejecting claim 55 also has not been established.

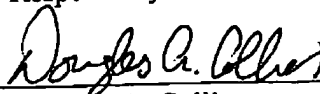
Claims 5-7, 11-14, 45-47, 51-54, 56-57, and 61-64, 67, and 69 depending from claims 1, 44 and 55 were rejected as being unpatentable over Baumgartner in view of Trieu and are allowable at least since the claim from which each depends is allowable and for other reasons provided in applications previous response.

Reconsideration and allowance of the present application including claims 1-14, 44-64, 67, and 69 is respectfully requested.

The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the present application.

Respectfully submitted

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